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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/332,866	06/15/99	LEVEUGLE B	A52026US

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EXAMINER	
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ART UNIT	PAPER NUMBER
1642	15

DATE MAILED: 05/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev.11/00)

1- File Copy

Office Action Summary

Application No.	Applicant(s)
09/332,866	Leveugle et al
Examiner	**Art Unit**
Minh-Tam Davis	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 5, 2001*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *14, 15, 17, 20, and 21* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *14, 15, 17, 20, and 21* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Effective February 7, 1998, the Group Art Unit location has been changed, and the examiner of the application has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Minh-Tam Davis, Group Art Unit 1642.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant cancels claims 1, 12, 13, 16, 18, 19, 24, 25, 27.

Accordingly, claims 14, 15, 17, 20 and 21 are being examined.

The following are the remaining rejections.

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

The supplemental information disclosure statement submitted on 03/14/01 could not be examined, because although the PTO-1449 is received by the Office, the references however are not received by the Office.

PRIORITY DATE

The priority date for the instant application is determined to be 06/15/98 in view of Applicant's arguments.

DEPOSIT REQUIREMENT

Rejection under 35 USC 112, first paragraph of claims 14 pertaining to deposit requirement remains for reasons already of record in paper No.12.

Applicant argues that the claimed hybridoma cell line AR47.47 was deposited with the American Type Culture on April 29, 1998.

Applicant's arguments set forth in paper No.13 have been considered but are not deemed to be persuasive for the following reasons:

Although the specification provides the name and accession number of the hybridoma cell line producing the claimed monoclonal antibody, the date of the deposition and the name of the depositor, where the cells are deposited, the specification fails to provide an adequate description of the claimed invention, e.g. address of of the depositor. Moreover, applicant is required to submit an affidavit or declaration stating that all restrictions upon public access to the deposits will be irrevocably removed upon the granting of a patent on this application, and that said hybridoma cell line will be replaced in the event that said hybridoma cell line dies.

The identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-1.809 for additional explanation of these requirements.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, NEW MATTER, NEW REJECTION

Claims 17 and dependent claims 14, 15, 20, 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way

as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 17 is amended to recite a method for inducing an immune response to prostate specific antigen, comprising administering a binding agent to "a patient".

A patient could be a patient with any disease other than prostate cancer. The specification does not disclose nor contemplate a method for inducing an immune response to prostate specific antigen, comprising administering a binding agent to "a patient" who has any disease.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, ENABLEMENT

Rejection under 35 USC 112, first paragraph of claims 14, 15, 17, 20, 21 pertaining to lack of enablement for a method for inducing an immune response to prostate specific antigen in a patient comprising administering a binding agent that specifically binds to an epitope comprising the sequence of SEQ ID NO:1, remains for reasons already of record in paper No.12.

Applicant argues that the specification clearly teaches in figure 9 and in examples 10 and 11 that administration of anti-PSA antibody or a binding agent that specifically binds to amino acids 139-163 of PSA, or SEQ ID NO:1 (i.e. antibody AR47.47-KLH) produces Ab3 antibody in both Balb/c and DBA mice as compared to the control mice.

Applicant's arguments set forth in paper No.13 have been considered but are not deemed to be persuasive for the following reasons:

Claim 17 is amended to recite a method for inducing an immune response to prostate specific antigen, comprising administering a binding agent to "a patient", wherein said binding agent binds to SEQ ID NO:1.

It is clear that the specification is drawn to therapy of prostate cancer, and the immune response in claim 17 is clearly meant to treat the "patient". As discussed in the previous Office action of paper No:12, pages 6-10, it is unpredictable that administration of a binding agent binds to SEQ ID NO:1 would reduce tumor growth for the following reasons: 1) In example 12 of the specification, inoculating mice first with PSA-transfected tumor cells, and then administer to said mice antibody AR47.47, no therapeutic effect was observed on tumor progression. 2) In example 11, although there is tumor regression in some mice, the tumor cells are injected into mice only after antibody treatment. Thus this example could not be applied to human patients because the specification does not disclose how to predict which individual would develop prostate cancer, nor exactly when said individuals would have prostate cancer to administer the claimed antibody before prostate cancer is detected. 3) Moreover, the results are highly variable even just within different types of mice. Even Applicant admits that the claimed tumor model would not reflect what is happening in human because prostate cancer is considered to be a slow progressing disease, whereas the growth rate of tumor in example 11 is much faster (p.39).

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

Rejection under 35 USC 112, first paragraph of claims 15, 17, 20, 21 pertaining to lack of enablement for a method for inducing an immune response to prostate specific antigen comprising administering a" binding agent" that specifically binds to an epitope comprising the sequence of SEQ ID NO:1, remains for reasons already of record in paper No.12.

Applicant argues that Examples 6, 7, 8, 10 and 11 teach administration of a binding agent that specifically binds to an epitope including SEQ ID NO:1 induces an anti-PSA response.

Applicant's arguments set forth in paper No.13 have been considered but are not deemed to be persuasive for the following reasons:

It is not clear how administration of a binding agent, such as a label, that specifically binds to an epitope comprising SEQ ID NO:1, i.e. prostate specific antigen (PSA), could elicit an immune response to prostate specific antigen, such as production of Ab2 (anti-idiotypic antibody) and Ab3 (anti-anti-idiotypic antibody) which is anti-PSA. The rejection remains because the scope of the claims must bear a reasonable correlation with the scope of enablement. See *In re Fisher*, 166 USPQ 19 24 (CCPA 1970). The scope of the claims broadly includes a method for inducing an immune response to PSA, which includes production of Ab3 which is anti-PSA, comprising administration of any binding agent that specifically binds to an epitope comprising SEQ ID NO:1, i.e. prostate specific antigen. The specification discloses that administration of anti-PSA antibodies and anti-SEQ ID NO:1 antibody, i.e. antibody AR47.47 produce Ab2 (anti-idiotypic antibody) and Ab3 (anti-anti-idiotypic antibody) against PSA. It is not clear how any binding agent, such as a label, could produce Ab3 which is specific for PSA. There is no correlation

between any binding agent to PSA and antibodies which could elicit anti-anti-idiotypic antibodies specific for PSA.

Further, MPEP 2164.08(a) teaches that a single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claims because the specification disclosed at most only those means known to the inventor. *In re Hyatt*, 708 F.2d 712, 714-715, 218 USPQ 195, 197 (Fed. Cir. 1983). In the instant application, the specification only discloses that administration of antibodies, either against PSA or against SEQ ID NO:1, would elicit Ab2 and Ab3, however, the scope of the claims encompass a method for for inducing an immune response to PSA, which includes production of Ab3 which is anti-PSA, comprising administration of any binding agent that specifically binds to an epitope comprising SEQ ID NO:1, i.e. prostate specific antigen. Thus the claims would be non-enabled according to MPEP 2164.08(a).

REJECTION UNDER 35 USC 102

Rejection under 35 USC 102 of claims 14, 15, 17 pertaining to anticipation by Giri et al remains for reasons already of record in paper No.12.

Applicant argues that claim 17, as amended, to require that the binding agent specifically binds an epitope comprising the sequence of SEQ ID NO:1 is not anticipated by Giri et al.

Applicant's arguments set forth in paper No.13 have been considered but are not deemed to be persuasive for the following reasons:

The language "comprising" reads on any amino acid sequence of any length, including full length PSA, provided it contains SEQ ID NO:1.

Giri et al teach administration of an antibodies specific for PSA, which would inherently comprise SEQ ID NO:1. Thus the method taught by Giri et al is the same as the claimed method.

REJECTION UNDER 35 USC 103

Rejection under 35 USC 103 of claims 14, 15, 17, 20, 21 pertaining to obviousness over Giri et al in view of Masuzawa et al, remains for reasons already of record in paper No.12.

Applicant argues that none of the cited references teach or suggest a binding agent that specifically binds an epitope comprising the sequence of SEQ ID NO:1.

Applicant's arguments set forth in paper No.13 have been considered but are not deemed to be persuasive for the following reasons:

Giri et al teach administration of an antibodies specific for PSA, which would inherently comprise SEQ ID NO:1.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The examiner can normally be reached on Monday-Friday from 9:30am to 3:30pm, except on Wesnesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4227.

Any inquiry of a general nature or relating to the status of thisplication or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

May 15, 2001

SUSAN UNGAR, PH.D
PRIMARY EXAMINER